UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,547	05/10/2001	David A. Sirbasku	057041-000004	6474

30565 7590 06/23/2009

WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/852,547	SIRBASKU, DAVID A.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *95-109* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *102-108* is/are allowed.

6)☒ Claim(s) *96-101 and 109* is/are rejected.

7)☒ Claim(s) *95* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 8, 2009 has been entered.

Claims 95-97 have been amended. Claims 95-109 are pending and under consideration.

Claim Objections

Claim 95 is objected to because of the following informalities: T47D is listed twice. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim109 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "H-301" in claim 109 lacks specific antecedent basis in claim 95.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 96-101 rejected under 35 U.S.C. 102(b) as being anticipated by Riss et al (In Vitro Cellular and Developmental Biology, 1989, Vol. 25, pp. 136-142, reference of the IDS filed April 11, 2003).

Claim 96 is drawn to a method comprising the steps of obtaining at least tow samples of identical mucosal epithelial cultured cells; treating one of said cell samples with polymeric IgM; leaving one pf said cell samples with out addition of polymeric IgM; incubating said samples under cell growth promoting conditions and measuring post-incubation cell population doublings in the cell samples. .

Claim 97 is drawn to a method comprising the steps of obtaining at least tow samples of identical mucosal epithelial cultured cells; treating one of said cell samples with plasma IgA; leaving one pf said cell samples with out addition of plasma IgA; incubating said samples under cell growth promoting conditions and measuring post-incubation cell population doublings in the cell samples.

Claim 98 is drawn to a method comprising the steps of adding an inhibitory amount of IgM to at least two samples of a maintained steroid hormone responsive cancer cell population in a nutrient medium; adding an amount of a substance of interest to one of the cell samples to yield a test mixture; incubating the cell samples for a period of time under cell growth promoting conditions and measuring the cell population in the cell samples after a period of time.

Claim 99 is drawn to a method comprising the steps of adding an inhibitory amount of IgA to at least two samples of a maintained steroid hormone responsive cancer cell population in a nutrient medium; adding an amount of a substance of interest to one of the cell samples to yield a test mixture; incubating the cell samples for a period of time under cell growth promoting conditions and measuring the cell population in the cell samples after a period of time.

Claim 100 is drawn to a method comprising the steps of adding an inhibitory amount of IgM to at least three samples of a maintained steroid hormone-responsive cancer cell population in a nutrient medium; adding an amount of the substance of interest to one of the cell samples to yield a test mixture; adding an amount of estrogen to one of the cell samples to yield a standard mixture; incubating the cell samples for a period of time under cell growth promoting conditions; and measuring the cell population in the cell samples after the period of time.

Claim 101 is drawn to a method comprising the steps of adding an inhibitory amount of IgA to at least three samples of a maintained steroid hormone-responsive cancer cell population in a nutrient medium; adding an amount of the substance of interest to one of the cell samples to yield a test mixture; adding an amount of estrogen to one of the cell samples to yield a standard mixture; incubating the cell samples for a period of time under cell growth promoting conditions; and measuring the cell population in the cell samples after the period of time.

It is noted that the recitation of a "method of detecting inhibition of steroid hormone responsive cell growth wherein the inhibition can be reversed by the steroid hormone", and a "method to detect estrogenic activity of a substance of interest" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is further noted that the phrases "wherein a lack of increase in the cell population doubling of the cell sample treated with polymeric IgM with respect to the untreated cell sample indicates that the cell growth in inhibited by polymeric IgM", "wherein a lack of increase in the cell population doubling of the cell sample treated with plasma IgA with respect to the untreated cell sample indicates that the cell growth in inhibited by plasma IgA", "wherein a significant increase in cell population doublings in the test mixture compared with the control mixture indicates that the substance possess estrogenic activity" are not given patentable weight when comparing the claims to the prior art as it simply expresses the intended result of a process step positively recited, see MPEP 2111.04.

The phrases "comparing the cell population doublings of the cell samples", "designating the cell samples without any substance of interest as a control sample" and "comparing the test mixture cell population doublings with the control mixture cell population doublings" do not have patentable weight because they are mental steps of abstract reasoning not requiring the transformation of matter. As clarified in In re Bilski, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir, 2008), a method claim must meet a specialized, limited meaning to qualify as a patent-eligible

process claim and the test for such a method claim is whether the claimed method is (1) tied to a particular machine or apparatus, or (2) transforms a particular article to a different state or thing, summarized as the "machine or transformation test". In the instant case, said "comparing" and "designating" require neither machine nor transformation and are therefore not patentable subject matter under 35 U.S.C. 101 and thus carry no patentable weigh within the context of the claim.

Riss et al disclose a method wherein the GHC1 rat pituitary cell line is grown in either serum free or serum supplemented growth medium and exposed to phenol red (a substance of interest) in the presence or absence of estrogen (Figure 2 and Figure 3). The presence of serum meets the specific limitation of treating on of said samples with polymeric IgM and treating one of said samples with plasma IgA because serum inherently comprises secretory immunoglobulins. The presence of serum also meets the limitation of an inhibitory amount o IgM and an inhibitory amount of IgA, because said inhibition is clearly reversed by the addition of estrogen in figure 2. The disclosure of Riss et al also meets the limitation of measuring post-incubation cell population doubling in the cell samples because that is the units indicated in figures 2 and 3, in addition to figures 4 and 5. The disclosure of Riss et al meets the limitation of claims 100 and 101 requiring at least three samples because the cell counts were from three wells and thus done in triplicate (Figures 2-5).

Given that the method of the prior art comprises the same method steps as claimed in the instant invention, , the claimed method is anticipated because the method will inherently be a method of detecting inhibition of steroid hormone responsive cell growth wherein the inhibition can be reversed by the steroid hormone, and a method to detect estrogenic activity of a substance of interest. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

All other rejections and objections as set forth or maintained in the prior Office action are withdrawn.

Claims 102-108 are allowable, pending the correction of the typographical error in claim 95.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643